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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,217	04/09/2001	Henry B. Kopf	2780-105 DIV 2	8633

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/829,217

Applicant(s)

KOPF, HENRY B.

Examiner

David A. Redding

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 188-212, 235-241, 244-249 and 252-280 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 188-212, 235-241, 244-249 and 252-280 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 188-212,235-241,244-249,252-280, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 4,885,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims of the instant device are the obvious operation of the device in the patented claims.

Claims 188-212,23-241,244-249,252-280, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,022,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims of the instant device are the obvious operation of the device in the patented claims.

Claims 188-212,235-241,244-249,252-280, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 1-13 of U.S. Patent No. 6,048,727. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broadly drafted and are considered to be anticipated by the patented claims.

Claims 188-212, 235-241, 244-249, 252-280, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,127,141. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broadly drafted and are considered to be anticipated by the patented claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States;

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 188,193,194,202,203,210,235,236, are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0220650 (Martinez).

The Martinez patent discloses a method of culturing cells using the tangential flow device illustrated in figure 3. The device is a hollow fiber reactor comprising hollow fibers (22). The fibers have selectively permeable walls for permitting passage of nutrients and chemical stimuli to the cells and permitting passage of waste into the interior of the fibers. The space surrounding the fibers is occupied by cells and is considered to be equivalent to the claimed first set of chambers and the interior of the fibers is for supplying nutrients to the cells and is considered to be equivalent to the claimed second set of chambers. The space outside the fibers is supplied through port 24 and media exits port 30. The interior of the fibers are accessed via ports 40,42.

The patent discloses that the temperature, pH, glucose, lactic acid is monitored, that fetal bovine serum is periodically added and that nutrient medium was continually provided. The medium reservoir and syringe are considered to read on the claimed reservoirs. See column 7.

Claims 188,193-210,235,236,240,244,245,246,248,249,252,253,254, are rejected under 35 U.S.C. 102(e) as being anticipated by USP 4,722,902 (Harm et al.).

Figure 2 illustrates the embodiment which reads on the claimed invention. The cell culturing system (10) includes a plurality of hollow fiber bioreactors (24) in flow communication with media reservoir (18) in a cell culturing loop (18) and a waste removal loop (16). The device allows for the permeate with media in (18) to be periodically removed and waste products separated in hollow-fiber reactor (50) through

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waste line (78) and the permeate and media returned to reservoir (18). Also, periodically, the product can be separated/concentrated in HBR (5) and harvested via flow line (82).

See col.3 thru col.6.

Claims 188-212,235,236,238-241,244-249,252-280, are rejected under 35 U.S.C. 102(e) as being anticipated by USP 4,889,812 (Guinn et al.).

Figure 1 illustrates the system which operation reads on the claimed method and device. The system (10) includes a hollow fiber bioreactor (HBR) (16) which is in a flow circuit which allows the direction of nutrient flow through the bioreactor (16) to be reversed (col.3, lines 54-58). The system includes a reversible pump (74) which allows in a first mode to circulate used nutrient media through the bioreactor, and in a second mode to add fresh nutrient media through inlet (88). The system also includes a second HBR (68) which allows for separation of cells from media. See col. 3, lines 54 thru col 5.

Response to Arguments

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., reversible flow) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-9178. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David A Redding
Primary Examiner
Art Unit 1744

DAR